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PATENT
Customer No. 22,852
Attorney Docket No. 08888.0500-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Francoise LECLERCQ *et al.*

Application No.: 09/783,981

Filed: February 16, 2001

For: PROCESS FOR PREPARING
FUNCTIONALIZED
POLYALKYLENEIMINES,
COMPOSITIONS CONTAINING
THEM AND USES THEREOF

)
)
) Group Art Unit: 1635
)
) Examiner: Janet L. Epps

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Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed September 19, 2002, the Examiner required
restriction under 35 U.S.C. § 121 among the following groups:

- Group I: Claims 23-38, allegedly drawn to a process for making
functionalized polyalkyleneimines, classified in class 536, subclass
55.3;
- Group II: Claims 39-41, allegedly drawn to a composition comprising at least
one polyalkyleneimine, classified in class 424, subclass 78.08; and
- Group III: Claim 42, allegedly drawn to a method for transferring nucleic acids
into cells, classified in class 435, subclass 455.

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Applicants provisionally elect to prosecute Group I, claims 23-38, allegedly drawn to a process for making functionalized polyalkyleneimines, with traverse. In particular, Applicants respectfully request the reconsideration and withdrawal of the requirement for restriction between elected Group I and Group II, which is allegedly drawn to a composition comprising at least one polyalkyleneimine.

The Examiner alleges that Groups I and II are related and distinct as a process of making and a product made by the process. According to the M.P.E.P., the groups are distinct if either or both of the following can be shown: (A) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products; or (B) that the product as claimed can be made by another and materially different process. *Id.* at § 806.05(f). The Examiner asserts that the product according to Group II can be made by a materially different process, and refers to page 6, lines 10-15, of the specification as-filed which states that "The polyalkyleneimines used in the present invention can be obtained according to various methods known to those skilled in the art. For example, they can be synthesized chemically by polymerization of the corresponding monomer(s)"

Applicants respectfully point out that the products as claimed are "functionalized polyalkyleneimines" not "polyalkyleneimines". Functionalized polyalkyleneimines are cationic polymers of a polyalkylimine type onto which targeting elements are covalently bonded. Specification at lines 23-25. Therefore, the "polyalkyleneimines", referred to by the Examiner as being capable of being made by another and materially different process, are only the starting material in the synthesis of the claimed "functionalized

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polyalkyleneimines". Restriction is therefore improper between these groups because the Examiner has provided no evidence to support a conclusion that the functionalized polyalkyleneimines of Group II can be made by a process materially different from that of Group I. Applicants request withdrawal of the restriction requirement between Groups I and II.

Applicants also respectfully request the reconsideration and withdrawal of the requirement for restriction between Groups II and III, which are allegedly drawn to a composition comprising at least one polyalkyleneimine and a method for transferring nucleic acids into cells, respectively. The Examiner alleges that Groups II and III are related and distinct as a product and a process of using the product. According to the M.P.E.P., the groups are distinct if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. *Id.* at § 806.05(h). The Examiner asserts that the product according to Group II can be used in a different process (e.g., as a soil-releasing agent as disclosed in WO 97/42285).

Applicants respectfully point out that the product as claimed is a functionalized polyalkyleneimine comprising, e.g., targeting elements such as sugars, proteins, and lipids, and nucleic acids such as DNA and RNA. As such, the product claimed is used as a vector for transferring nucleic acids into cells. There is no teaching or suggestion in WO 97/42285 that a similarly functionalized polyalkyleneimine comprising targeting elements and nucleic acids can be used as a soil-releasing agent. Restriction is therefore improper between these groups because the Examiner has provided no

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evidence to support a conclusion that the composition of Group II can be used in a materially different process than that of Group III. Applicants request withdrawal of the restriction requirement between Groups II and III.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 31, 2002

By: 
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